

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CCF-6566PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US04/12882	International filing date (day/month/year) 27 April 2004 (27.04.2004)	Priority date (day/month/year) 29 April 2003 (29.04.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/68; C12P 19/34; C07H 21/04 and US Cl.: 435/6, 91.1, 91.2; 536/23/1, 24.3		
Applicant THE CLEVELAND CLINIC FOUNDATION		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>—</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 02 November 2004 (02.11.2004)	Date of completion of this report 20 July 2005 (20.07.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPBA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Jehanne S. Sitton Telephone No. (571) 272-1600 <i>Valerie Bell-Harris</i> <b>JEHANNE SITTON</b> <b>PRIMARY EXAMINER</b>	

Form PCT/IPEA/409 (cover sheet)(July 1998)

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-21 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages 22-26, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages 1-3, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages 1-176, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☒ The amendments have resulted in the cancellation of:**

- ☒ the description, pages none
- ☒ the claims, Nos. none
- ☒ the drawings, sheets/fig none

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US04/12882**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>6-12, 17, 18, 21-30</u>	YES
	Claims <u>1-5, 13-16, 19, 20</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-30</u>	NO
Industrial Applicability (IA)	Claims <u>1-30</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-5, 13-16, 19, and 20 lack novelty under PCT Article 33(2) as being anticipated by Genbank Accession Number U21676. Genbank Accession Number U21676 teaches the sequence of SEQ ID NO: 1. The complement of this sequence would hybridize to SEQ ID NO: 1 and SEQ ID NO: 2. This sequence is considered 'derived' from SEQ ID NO 1. This sequence comprises the sequences of each of SEQ ID NOS 6-9. This sequence comprises the sequences of the prgH, prgI, prgJ, and prgK genes of Salmonella.

Claims 6-12, 17, 18, and 21-20 lack an inventive step under PCT Article 33(3) as being obvious over Genbank Accession Number U21676 in view of Daum et al.

Genbank Accession Number U21676 teaches the sequence of SEQ ID NO: 1. The complement of this sequence would hybridize to SEQ ID NO: 1 and SEQ ID NO: 2. This sequence is considered 'derived' from SEQ ID NO 1. This sequence comprises the sequences of each of SEQ ID NOS 6-9. This sequence comprises the sequences of the prgH, prgI, prgJ, and prgK genes of Salmonella. Genbank Accession number does not teach primers for the prg gene of Salmonella, fluorescently labeled probes, a method of detecting Salmonella, or a kit comprising a primer and a probe for the prg gene of Salmonella. However Daum et al teaches a method of detecting Salmonella by using PCR primers and fluorescently labeled probes directed to the invA gene of Salmonella (see page 3050, col. 1) in a real time PCR assay (see page 3051, col. 1), for the purpose of detecting Salmonella. Therefore, it would have been obvious to one of ordinary skill in the art to construct primers and fluorescently labeled probes directed to the prg gene as set forth in Genbank Accession Number U21676 for the purpose of detecting Salmonella because Daum et al teach that primers and probes directed to genes from Salmonella can be used to detect Salmonella. It would have also been obvious to the ordinary artisan to package such primers and probes in a kit to make the method of detecting Salmonella as taught by Genbank Accession Number U21676 in view of Daum et al more convenient to perform.

none